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10/568,056	07/13/2007	Thomas G. Eakin	53015-7004	3694

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EXAMINER

TREYGER, ILYA Y

ART UNIT	PAPER NUMBER
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3761

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11/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,056	Applicant(s) EAKIN, THOMAS G.	
	Examiner ILYA Y. TREYGER	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 4, and 20 are amended.
2. Claims 5 and 23 are canceled.
3. Claims 1-4 and 6-22 are examined on the merits.

Response to Arguments

4. Applicant's arguments filed 08/18/2008 have been fully considered but they are not persuasive:

5. With respect to claim 1, Applicant argues that Cuschieri does not teach the bag comprising two chambers, but teaches one single chamber comprising the iris valve.

However, in accordance with definition the "chamber" is an "enclosed space" (See *The American Heritage® Dictionary of the English Language, Fourth Edition*). Applicant is referred to Cuschieri, Fig. 3C, where two enclosed spaces have been clearly depicted. As such two chambers have been disclosed by Cuschieri.

6. In response to applicant's argument that the references fail to teach that the two chambers are in the bag, it is noted that the tube shown in Fig. 3c is accommodated inside the bag, and therefore, the two chambers of this tube are also inside the bag.

7. Applicant further argues that Cuschieri contains no teaching of a flexible partition separating first and second chambers and including a valve for inhibiting the passage of fluid between the chambers.

However, Cuschieri expressly discloses a tube 13 (Fig. 5) made of elastic material (Col. 4, line 18), which is a flexible partition separating the second chamber from the first chamber, and an access opening 5 (Fig. 3d) for sealingly receiving a tool (Col. 3, lines 37, 38), and

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therefore is acting as a valve fully capable of inhibiting the passage of fluid between the chambers.

8. Applicant further argues that the combination of Cuschieri and Beevers is improper because a cover of Beevers is intended for the tracheotomy tube, and therefore the person of ordinary skill in the art would certainly not affix the tracheal tube as a closure in the opening, which is designated by Examiner to be the closable opening of one chamber.

However, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The inventions of Cuschieri and Beevers belong to the same problem solving area, i.e. maintaining the body fistula, and therefore the combination is proper.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-4, 8, 9, 12, 13, 15-19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuschieri et al. (US 5,480,410) in view of Beevers (US 4,802,474).

12. In Re claim 1, Cuschieri discloses a fistula isolating bag comprising:

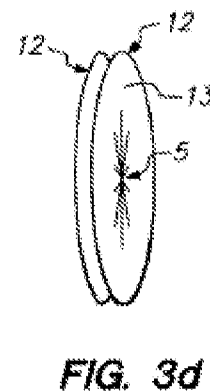
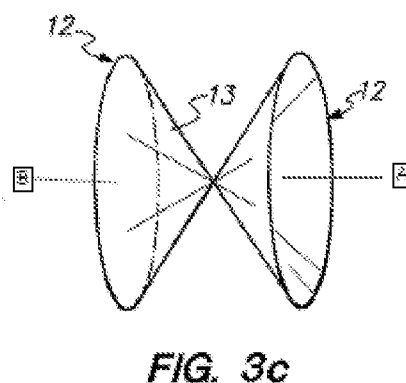
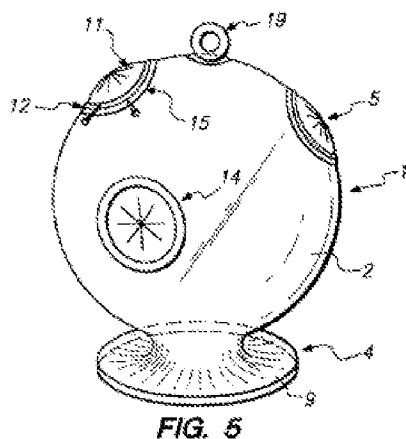
a bag 2 (Fig. 5) having a closable entrance 5 (Col. 3, lines 37, 38; Fig. 5);

a flange 9 (Col. 4, line 10; Fig. 5), which is an attachment means for affixing the bag to the skin of a patient;

a first chamber A (Fig. 3c) having entrance fully capable of being closed;

a second chamber B (Fig. 3c) wherein access to the second chamber is made through the first chamber via a valve 5 (Figs. 5 and 3d) arranged to inhibit passage of fluid from the second chamber to the first and to allow said access from the first chamber to the second.

a tube 13 (Fig. 5) made of elastic material (Col. 4, line 18), and the separation of two chambers made of a flexible material makes the separation line (partition) flexible..



Cuschieri does not expressly disclose the fistula isolating bag comprising a closure for the closable entrance.

Beevers teaches the use of protective cover 11 for fistula access appliances (Fig. 2).

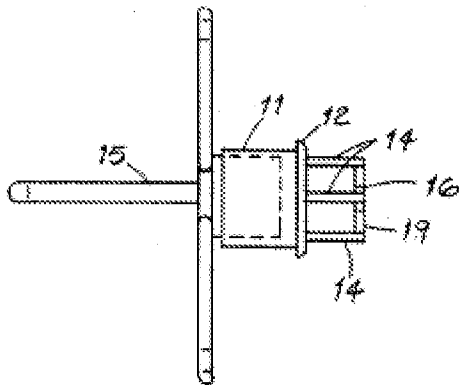


FIG. 2.

Since both Cuschieri and Beevers belong to the same problem solving area, i.e. maintaining the body fistula, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fistula isolating bag of Cuschieri with the protective cover, as taught by Beevers, because such modification would provide the first chamber with isolation from the external air potentially pathogenic content.

13. In Re claim 2, Cuschieri in view of Beevers disclose the invention discussed above, but do not expressly disclose that the closable entrance is sealable.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the closable entrance sealable because it is the requisite condition for providing the closure with isolating features.

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14. In Re claim 3, Cuschieri discloses the bag wherein said valve includes at least two members which extend inside the bag and, when the closure is in a closed state, said members close to form the valve (Figs. 3c and 3d).

15. In Re claim 4, Cuschieri in view of Beevers disclose the bag wherein the valve comprises a flexible partition dividing the first and second chambers (Fig. 3c) and comprising first and second adjacent layers of material 12 (Fig. 3d) including an aperture 12 (Fig. 3c), but do not expressly disclose the valve comprising the first and second layer, wherein the first layer has a first aperture and the second layer has a second aperture.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the valve of two apertures belonging to two separated layers in order to improve the valve with the sluice effect, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

16. In Re claim 8, Cuschieri in view of Beevers disclose the invention discussed above, but do not expressly disclose the deference in weight of layers.

The deference in weight of layers has been determining by the gravitation force desired to keep the bag in its place, and therefore is the matter of optimization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the layers by weight depending of the gravitation desired to keep the bag in its place because it involves only routine skills in the art.

17. In Re claim 9, Cuschieri in view of Beevers disclose the invention discussed above but do not expressly disclose the deference in thickness of layers.

The deference in thickness of layers has been determining by the weight of layers desired to provide the grade of gravitation necessary for keeping the bag in its place during the fistula maintenance, and therefore is the matter of optimization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the layers by thickness depending of the desired weight of layers because it involves only routine skills in the art.

18. In Re claim 12, Cuschieri discloses the bag wherein the bag comprises first and second bag portions, the first chamber being formed by the first bah portion and the second chamber is fully capable to be formed by the second bag portion (Figs. 5 and 3c).

19. In Re claim 13, Cuschieri discloses the invention discussed above, but does not expressly disclose the closable entrance located on the outer edge of the first chamber.

Beevers teaches the closable entrance located on an outer edge of the first chamber (Fig. 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to locate the closable entrance of Cuschieri on an outer edge of the first chamber, as taught by Beevers, because such modification would provide the first chamber with isolation from the external air potentially pathogenic content.

20. In Re claim 15, Cuschieri discloses the invention discussed above, but does not expressly disclose the closable entrance comprising a removable cover.

Beevers teaches the closure being a removable cover (Fig. 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fistula isolating bag of Cuschieri with the

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removable cover, as taught by Beevers, because such modification would convenience to maintain the fistula.

21. In Re claim 16, Cuschieri discloses the bag including the aperture 12 (Fig. 3c) for the passage of fluid between atmosphere and the device.

22. In Re claim 17, Cuschieri discloses the bag wherein the aperture comprises a drain (Fig. 3c) since the aperture is fully capable to perform draining functions.

23. In Re claim 18, Cuschieri discloses the bag wherein the outer surface of the second chamber is fully capable to be adherent (Figs. 3c and 3d).

24. In Re claim 19, Cuschieri in view of Beevers do not expressly disclose the particular parameter of the overall dimension of the first chamber.

The overall dimension of the first chamber depends of the instrument type being used for maintaining the fistula what in its turn depends of the fistula character (abdominal fistula, tracheostome, pleura fistula, etc.) and particular disease suffered by patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the overall dimension of the first chamber depending of the instrument type being used for maintaining the fistula, fistula character, and particular disease suffered by patient because it involves only routine skills in the art.

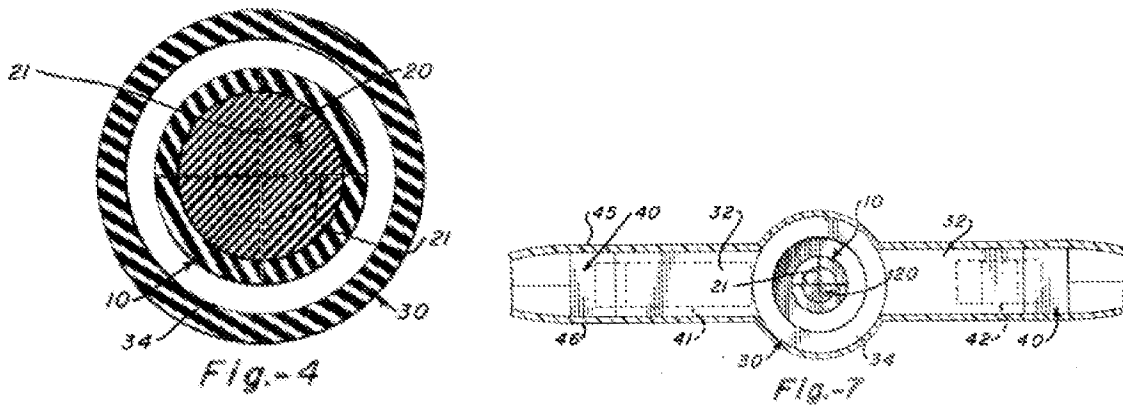
25. In Re claim 21, Cuschieri discloses the bag made of polyethylene (Col. 2, ln. 1-2).

26. Claims 6, 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuschieri et al. (US 5,480,410) in view of Beevers (US 4,802,474), as applied to claim 4 above, and further in view of Arenberg et al. (US 4,175,563).

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27. In Re claim 6, Cuschieri in view of Beevers disclose the invention discussed above, except for the bag wherein each aperture comprises a respective slit.

Arenberg teaches the use of slit valve in implantable shunts (fistula) (See Figs 4 and 7).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aperture closure of Cuschieri/ Beevers with the slit valve, as taught by Arenberg, because such modification would convenience the medical treatment access into the first chamber of the bag.

28. In Re claim 7, Cuschieri in view of Beevers and further in view of Arenberg disclose the slit valve comprising plurality of slits (Figs. 4 and 7), but do not expressly disclose the slits extending generally parallel to one another.

Since the criticality of positioning the slits parallel to one another claimed by Applicant is not supported by any showing of criticality of such positioning in the instant specification, nor did Applicant stated that such positioning of slits serves any specific purpose or performs any specific function other than the function disclosed in Arenberg, it would have been obvious to those skilled in the art at the time the invention was made to position the slits parallel to one another as an obvious design choice, and as such it does not impact the patentability of claim 7.

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29. In Re claims 10 and 11, Cuschieri in view of Beevers and further in view of Arenberg disclose the invention discussed above, but do not expressly disclose the bag wherein the slits are between 80 and 300 mm long and wherein offset between the slits is between 5mm and 100 mm.

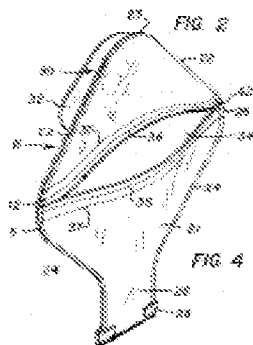
The length range of slits and the offset range between slits depend of the diameter range of the aperture which in its turn depends of the instrument type being used for maintaining the fistula what in its turn depends of the fistula character (abdominal fistula, tracheostome, pleura fistula, etc.) and particular disease suffered by patient.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the slits length range and the offset range between slits depending of the diameter range of the aperture because it involves only routine skills in the art.

30. Claims 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuschieri et al. (US 5,480,410) in view of Beevers (US 4,802,474), as applied to claim 4 above, and further in view of Brown et al. (US 3,618,606).

31. In Re claim 14, Cuschieri in view of Beevers disclose the invention discussed above, but do not expressly disclose the bag wherein the closure is a zip fastener.

Brown teaches the use of zip fastener in the fistula appliance (Fig. 2).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fistula isolating bag of Cuschieri/ Beevers with the closure comprising a zip fastener, as taught by Brown, because such modification would simplify the operative access into the first chamber.

32. In Re claim 20, Cuschieri in view of Beevers disclose the claimed invention discussed above but do not expressly disclose the flexible vessel joint with the fistula appliance.

Brown teaches the stoma bag (flexible vessel) joined to the fistula appliance (Fig. 7).

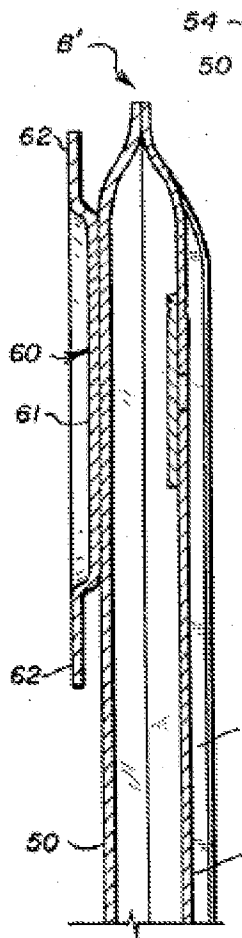


FIG. 7

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fistula isolating bag of Cuschieri/ Beevers with the flexible vessel (stoma bag), as taught by Brown, because such modification would provide let the product to provide collection of the body fluids.

Cuschieri in view of Beevers and further in view of Brown do not expressly disclose the presence of two identical slit valves positioned adjacent the joint.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use two identical slit valves in order to strength the valve features of the joint since the mere duplication of the essential working parts of a device involves only routine skill in the art.

33. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cuschieri et al. (US 5,480,410) in view of Beevers (US 4,802,474), as applied to claim 12 above, and further in view of Steer (US 5,976,118).

Cuschieri in view of Beevers disclose the invention discussed above, except for the bag wherein the joint between the first and second chamber is made by a welding process selected from the group consisting of thermal, radio-frequency and impulse welding.

Steer teaches the use of welding process selected from thermal or radio-frequency welding to form joints between fistula appliance elements (Col. 5, ln. 40-41).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fistula isolating bag of Cuschieri/ Beevers with the welded joint between chambers, as taught by Steer, because such modification would improve the mechanical reliability of the product.

Conclusion

34. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/
Examiner, Art Unit 3761

***/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761***